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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
HURT, SHARON L	

ART UNIT	PAPER NUMBER
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/647,919	DOMINOWSKI, PAUL JOSEPH	
	Examiner	Art Unit	
	Sharon Hurt	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-83* is/are pending in the application.

4a) Of the above claim(s) *8-19,28-75 and 80-82* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,20-27,76-79 and 83* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *Dec 30 2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, Claims 1-11, 20-31 and 76-83, and *Leptospira borgpetersenii hardjo-bovis* in the reply filed on April 10, 2006 is acknowledged. The traversal is on the ground(s) that Groups I-III are all directed to subject matter classified in the same class therefore examination of all three groups would not constitute burden on the Examiner. This is not found persuasive because the method or treating or preventing disease would require a separate search for additional components and limitations.

The requirement is still deemed proper and is therefore made FINAL.

Claims 8-19, 28-75 and 80-82 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on April 10, 2006. Claims 1-7, 20-27, 76-79 and 83 are examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-6, 25-26 and 79 contain the trademark/trade name *Amphigen*. Where a trademark or trade name is used in a claim as a limitation to identify or describe a

particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe an adjuvant and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 7, 20-21, 27; and 76 are rejected under 35 U.S.C. 102(b) as being anticipated by Talens et al. (Journal of the American Veterinary Medical Association, May 1, 1989, Vol. 194, No. 9, pages 1273-1280).

The claimed invention is drawn to an immunogenic composition comprising: a modified live Bovine Herpes Virus (BHV-1); a modified live parainfluenza virus Type 3 (PI-3); a modified live Bovine Respiratory Syncytial Virus (BRSV); an adjuvant; at least

one antigen; and a veterinary-acceptable carrier, wherein said antigen is inactivated, wherein said antigen comprises one antigen, *Leptospira borgpetersenii hardjo-bovis*.

Talens et al. discloses efficacy of viral components of a combination vaccine for prevention of respiratory and reproductive system diseases in cattle. Talen discloses a combination vaccine comprising: infectious bovine rhinotrachetitis virus (IBRV), caused by bovine herpes virus 1 (BHV-1) (Yancey, see reference U); parainfluenza typr-3 (PI-3) virus; bovine diarrhea virus (BVDV); respiratory syncytial virus (RSV); and leptospirosis (page 1273, Summary). The multivalent vaccine consists of modified live IBRV, PI-3 virus and RSV strains; an inactivated BVDV and 5 Leptospira serovars (including *hardjo*) (page 1273, second column). The BVDV component was a combination of a cytopathic strain and noncytopathic strain, chemically inactivated and combined with an aluminum hydroxide adjuvant (page 1273, second column).

Claims 1-2, 7, 20-21, 27; and 76 are rejected under 35 U.S.C. 102(b) as being anticipated by Bowland et al. (Canadian Veterinary Journal, Jan 2000, Vol. 41, No. 1, pages 33-48). The claimed invention is described above. Boland et al. discloses current commercial vaccines available in Canada for bovine respiratory disease. Vaccines include infectious bovine rhinotrachetitis virus [(IBRV), bovine herpesvirus-1, (BHV-1)], bovine viral diarrhea virus (BVDV), bovine respiratory syncytial virus (BRSV), parainfluenza-3 virus (PI-3), and bacterial antigens including *Leptospira* serovars (page 33 and Table 1 pages 43-45). Some of the multi-vaccines included adjuvants (Table 1, pages 43-45).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-7, 20-27, 76-79 and 83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Talens et al. (Journal of the American Veterinary Medical Association, May 1, 1989, Vol. 194, No. 9, pages 1273-1280) **or** Bowland et al. (Canadian Veterinary Journal, Jan 2000, Vol. 41, No. 1, pages 33-48) as applied to claims 1-2, 7, 20-21, 27; and 76 above, and further in view of Barr et al., (Advanced Drug Delivery Reviews, 1998, Vol. 32, No. 3, pages 247-271), Pruette et al., (Veterinary Parasitology, 1995, Vol. 58, No. 1-2, pages 143-153), and Wilson et al., (Canadian Journal of Veterinary Research, Oct 1995, Vol. 59, No. 4, pages 299-305).

The claimed invention is drawn to an immunogenic composition comprising: a modified live Bovine Herpes Virus (BHV-1); a modified live parainfluenza virus Type 3 (PI-3); a modified live Bovine Respiratory Syncytial Virus (BRSV); an adjuvant; at least one antigen; and a veterinary-acceptable carrier, wherein said antigen is inactivated, wherein said antigen comprises one antigen, *Leptospira borgpetersenii hardjo-bovis*, wherein said adjuvant comprises saponin, wherein said adjuvant comprises saponin

containing oil-in-water emulsion, wherein said adjuvant comprises Quil A, Amphigen and cholesterol oil-in-water emulsion is microfluidized.

The teaching of Talen and Bowland are described above. Talen or Bowland do not teach the addition of adjuvants: Quil A, Amphigen and cholesterol oil-in-water emulsion in micro-fluidized form.

Barr et al., teaches the use saponins for animal vaccines, formulation of saponins and adjuvant activity (page 247, Abstract). Barr teaches Quil A (Quillaia saponins), a cholesterol and phospholipids, is a highly active adjuvant used in a number of veterinary vaccines (page 249, first column). Quil A, a purified material, had a predictable adjuvant activity with less local toxicity in cattle than an equivalent amount of crude saponin (page 249, first column).

Pruette et al. teaches a study evaluating two veterinary acceptable adjuvants, alhydrogel (aluminum hydroxide gel suspension) and amphigen (alone and in combination) (page 143, Abstract). A mixture of alhydrogel and amphigen (a mineral oil-based adjuvant) induced the highest serum antibody response (page 143, Abstract). All adjuvants evaluated induced comparable immediate-type skin test responses, and the mixture of alhyrogel and amphigen was best in terms of delayed-type skin reaction and resultant cellular infiltration at the reaction site (page 143, Abstract). Pruette suggests that this mixture would be worthy of further efficacy investigation in a vaccine formulation (page 143, Abstract).

Wilson et al., teaches a comparison of tissue reaction and immunity in a vaccine for swine using a wide variety of adjuvants (page 299, first column). The adjuvants

used were from vegetable oil, mineral oil, aluminum hydroxide, polyethylene glycol, Quil A and Amphigen (page 299, first column). The trials showed that bacterins containing mineral oil adjuvant induced better protection than do bacterins containing aluminum hydroxide (page 299, second column).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to add an adjuvant to the mulit-viral and bacterial antigen vaccine for increased antibody response, less toxicity and lessened skin reaction.

The person of ordinary skill in the art would have been motivated to make that (those) modification(s) because of the teachings of Barr and Pruette and reasonably would have expected success because of the adjuvant comparison results of Wilson.

Conclusion

The teaching of Talen and Bowland, on multi-viral vaccines for bovine, in further view of the teaching of adjuvants by Barr, Pruette and Wilson have met every limitation of the instant claimed invention.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Fulton et al., (Vaccine, 1995, Vol. 13, No. 8, pages 725-733), Cortese et al., (Large Animal Practice, Sept./Oct. 1997, Vol. 15, No. 5, pages 18-24) and Copland et al., (International Journal of Pharmaceutics, 2000, Vol. 196, pages 135-139).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon Hurt whose telephone number is 571-272-3334. The examiner can normally be reached on M-F 8:00 - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Housel James can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharon Hurt

April 24, 2006

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